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VIA FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: ANDA Suitability Petition for Amlodipine Besylate - 2005P-0066/CP1

Submission of Pediatric Studies Waiver Request

Dear Sir/Madam:

On February 11, 2005, we submitted a Suitability Petition for Amlodipine Besylate Capsules 2.5, 5, and 10 mg for a proposed dosage form change from an immediate release tablet to an immediate release capsule.[1] This was assigned docket number 2005P-0066/CP1. By this letter we are requesting a waiver of pediatric studies as required under the Pediatric Research Equity Act of 2003. Pediatric studies have been conducted on Amlodipine Besylate and Pfizer has been granted six months of pediatric exclusivity for the patents for Norvasc® (amlodipine besylate) Tablets that are listed in the Orange Book.

Current labeling for Pfizer's Norvasc provides the following information on the clinical study in pediatric patients that was conducted:

> Pediatric Patients: Two hundred sixty-eight hypertensive patients aged 6 to 17 years were randomized first to NORVASC 2.5 or 5 mg once daily for 4 weeks and then randomized again to the same dose or to placebo for another 4 weeks. Patients receiving 5 mg at the end of 8 weeks had lower blood pressure than those secondarily randomized to placebo. The magnitude of the treatment effect is difficult to interpret, but it is probably less than 5 mmHg systolic on the 5 mg dose. Adverse events were similar to those seen in adults.

[1] At the time the petition was submitted I was a partner at the law firm of DLA Piper Rudnick Gray Cary US LLP. I am currently a partner at the law firm of Foley and Lardner LLP. Please transmit all correspondence regarding this petition to the address on the letter head above.

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Based on the fact that pediatric studies have already been conducted on Amlodipine Besylate tablets, we are requesting a pediatric wavier for the product proposed under the above-referenced suitability petition.

Sincerely,

David L. Rosen, B.S. Pharm., J.D.